

REMARKS

Claims 1-34 were originally filed in the present application. Of the pending claims, Claims 1-24 and 28 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for “a pair of antibodies specific to PrP^{SC}.¹” Claims 25-27 and 29-34¹ stand rejected under 112, second paragraph, as being incomplete for omitting essential elements. Claim 32 has also been rejected under 112, second paragraph, for insufficient antecedent basis for the phrase “labeled antibody.” Applicant respectfully traverses these improper rejections and in response repeats and incorporates for the present Reply all the reasons set forth in the Reply dated February 13, 2004. However, in the interest of moving prosecution forward for substantive examination, Claims 1, 14, 28 and 32 have been amended to obviate the 112 rejections. Reconsideration of all pending claims on the merits based on the following remarks is earnestly sought.

With respect to Claim 25-27 and 29-32, however, Applicant strongly traverses the rejection under 35 U.S.C. 112, second paragraph, referencing MPEP § 2172.01. First, the referenced section invokes the first paragraph of 112 against claims “which omit matter disclosed to be essential to the invention as described in the specification or in other statements of record.” The second paragraph of 112 is invoked where a claim fails to interrelate essential elements of the invention as defined by applicant in the specification. Such does not appear to be the Examiner’s rejection

Second, the invocation of this rejection is improper because the specification does not identify the antibodies specific to PrP^{SC} as critical elements. The Examiner’s placement of criticality are of no moment. This is supported with reference to MPEP § 2164.08(c), which states:

“In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).”

§ 2164.08(c) goes on to state:

¹ The PTO Action only indicates Claims 25-27 and 29-32. However, as no claims have been indicated as allowable, this rejection appears to be directed to Claims 25-27 and 29-34.

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“. . . an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended.” [Emphasis added]

No such statement of criticality is ever made in the present application, and the Examiner has pointed to none. Rather, the Examiner identifies the “omitted elements” with the following *non sequitur*:

“how one assays for only PrP^{SC} by using an immunochromatographic technique when there are no discriminating elements, e.g., antibodies specific to PrP^{SC} being utilized.”

While the use of antibodies specific to PrP^{SC} are described as preferred, the possibility of other techniques known by those skilled in the art is not dismissed by the specification. In fact, the specification is not required to teach every known embodiment. The enablement of Claim 25 is to be considered in light of what any person skilled in the art would understand the invention to be (see 35 U.S.C. 112). Claim 25 does not omit the use of discriminating elements as the Examiner suggests, it merely claims them using broader language, i.e., immunochromatographic technique. To the extent that no other techniques are known, then the scope of Claim 25 would be limited to the use of discriminating elements.

Accordingly, reconsideration of Claims 25-27 and 29-32 is respectfully requested. Withdrawal of the rejection under 35 U.S.C. 112, second paragraph, is earnestly sought.

As to the remaining claims, Claims 1, 14 and 28 have been amended to add language to positively state that the two antibodies are different. Claim 32 has been amended to change dependency to provide proper antecedent basis for the term “labeled antibody”.

Reconsideration of the present rejection is requested, and a substantive examination of the pending claims is earnestly sought.

CONCLUSION

Claims 1-34 are presently pending in the referenced application. Amendments have been made to the claims to move prosecution forward. Applicant believes that all pending claims are allowable, and a notice to that effect is earnestly sought at the Examiner's earliest convenience. Reconsideration of all pending claims is hereby requested. If any informalities remain which may be cleared up by Examiner amendment, Applicant requests the Examiner to call the undersigned attorney at his convenience.

The Commissioner is authorized to debit or credit our Deposit Account No. 23-0280 for any payment **deficiencies or overpayments** associated with this matter.

Respectfully submitted,

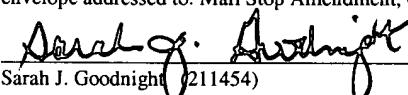

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CERTIFICATE OF MAILING (37 C.F.R. § 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on October 19, 2004.


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